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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|---------------------------|---------------------|------------------|
| 10/500,662 | 02/10/2005 | Natalie Elizabeth Beesley | ISA-026.01 | 2468 |

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| EXAMINER |
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NGUYEN, BAO THUY L

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| ART UNIT | PAPER NUMBER |
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1641

DATE MAILED: 11/02/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

14

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|------------------------------|------------------------|---------------------|--|
| Office Action Summary | Application No. | Applicant(s) | |
| | 10/500,662 | BEESLEY ET AL. | |
| | Examiner | Art Unit | |
| | Bao-Thuy L. Nguyen | 1641 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 July 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-14 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-14 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date: _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date: _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. The preliminary amendment submitted on 02 July 2004 has been received. Claims 1-14 are pending.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 1-14 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is indefinite because it is unclear how the presence or amount of analyte is detected. The claim recite means for generating a signal but does not state how the means for generating the signal is specific for the analyte.

Claim 2 is not further limiting claim 1 from which it depends because the analyte cannot be part of the device of claim 1. Usually, analytes are collected at the time of the assay and is not included in the manufacturing of the device.

Claims 2-9 and 14, "A device" should be changed to -The device—for clarity.

Claim 9 is confusing. It is unclear where these "depots" are located on the test device relative to the means for generating the signals.

Claim 10 is vague because it lacks a correlation step. How do the signals relate to the presence of the analyte?

Claims 11-14, "A device" should be changed to -The device – for clarity.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

5. Claims 1, 3, 6, 9, 10, 11, 12 and 14 are rejected under 35 U.S.C. 102(e) as being anticipated by Mendel-Hartvig et al (US 7,018,847).

Mendel discloses an assay device for determining an analyte comprising a flow matrix having an application zone, a detection zone having an immobilized capture agent capable of directly or indirectly binding to the analyte. A wicking member and a time indicator downstream of the detection zone for indicating when liquid applied to the liquid application zone has reached the time indicator. The time indicator comprises an indicator substance capable of exhibiting a visible color change when

hydrated by the liquid. Mendel teaches that the time indicator can be placed at variable distance on the flow matrix thereby permitting variation of the time elapsing. See column 2, line 35 through column 3, line 5. Mendel also teaches a method of using the device for detecting analytes such as proteins, haptens and hormones. See column 8, lines 29-35. Mendel teaches that the chemical timer is located on a pad and the housing part that covers the pad is transparent or translucent or has an opening to permit the color change to be observed (column 6, lines 3-20), and that the color change of the time indicator signals that the assay result may be read (column 7, lines 46-47). Mendel discloses that the time of color change is controlled through the position of the time indicator in the device and discloses several different time changes as exemplary evidence. See column 8, line 54 through column 9, line 28.

6. Claims 1-6 and 9-14 are rejected under 35 U.S.C. 102(b) as being anticipated by May et al (US 5,602,040).

May teaches an assay device comprising a hollow casing constructed of moisture-impervious solid material containing a dry porous carrier which communicates directly or indirectly with the exterior of the casing such that a liquid test sample can be applied to the porous carrier. The device contains a labeled specific binding reagent for an analyte. The labeled specific binding reagent is freely mobile within the porous carrier when in the moist state, and unlabeled specific binding reagent for the same analyte, which unlabeled reagent, is permanently immobilized in a

detection zone on the carrier material. (Column 2, lines 3-20). May teaches an embodiment where the device contains a control zone loaded with an antibody that will bind to the labeled antibody from the first zone; or the control zone can contain an anhydrous reagent that when moistened, produces a color change or color formation (i.e. time indicator). See column 5, lines 8-27. May teaches the use of direct labels such as minute colored particles, such as dye sols, metallic sols and colored latex particles (column 3, lines 22-32). May teaches a plurality of detection zones arranged in series on the porous solid phase material through which the aqueous liquid sample can pass progressively, can also be used to provide a quantitative measurement of the analyte or can be loaded individually with different specific binding agents to provide a multi-analyte test (column 9, lines 19-30). Quantitative measurement may be done visually by eye or by instrument. May teaches backing the porous nitrocellulose sheet with plastic to increase handling strength (column 7, lines 15-20). Specifically, May teaches laminating the porous carrier to a transparent moisture-impermeable plastic material and that the transparent strip is in contact with the upper inner surface of the casing (column 14, lines 33-41). May also teaches an absorbent sink provided at the distal end of the carrier material to aid in the flow of sample and to ensure that excess labeled reagent from the first zone which does not participate in any binding reaction in the second zone is flushed away from the detection zone (column 5, line 58 through column 6, line 6). May teaches that the flow rate characteristics of the porous carrier material can be selected to allow adequate reaction times during which the binding reaction can

occur. Controls over these parameters can be achieved by the incorporation of viscosity modifiers such as sugars and modified celluloses to slow down the reagent migration (column 7, lines 30-39).

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. Claims 7 and 8 are rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Mendel-Hartvig et al.

See the discussion of Mendel above. This reference differs from the instant invention in failing to teach that the signal development time is about 8 or 10 seconds. However, Mendel specifically teaches that the time indicator can be placed at variable position along a pad to permit variation of the time elapsing from the application of the liquid until the indicator substance changes color. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to place the time indicator at any variable position to achieve the time desired.

Furthermore, it has long been settled to be no more than routine experimentation for one of ordinary skill in the art to discover an optimum value of a result effective

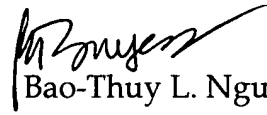
variable and since Applicant has not disclosed that the specific limitations recited in instant claims are for any particular purpose or solve any stated problem and the prior art teaches that such time can be varied according to specific needs absent unexpected results, it would have been obvious for one of ordinary skill to discover the optimum workable ranges of the methods disclosed by the prior art by normal optimization procedures known in the art.

Conclusion

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bao-Thuy L. Nguyen whose telephone number is (571) 272-0824. The examiner can normally be reached on Tuesday and Wednesday from 8:00 a.m. -4:30 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long V. Le can be reached on (571) 272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.


Bao-Thuy L. Nguyen
Primary Examiner
Art Unit 1641 10/26/06